Notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0300]

Determination That Diclofenac Potassium 25-Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that diclofenac potassium 25-milligram (mg) tablet (Cataflam) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diclofenac potassium 25-mg tablet.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness § 314.62 (21 CFR 314.162)). Regulations also provide that the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On June 27, 2003, The Weinberg Group, Inc., submitted a citizen petition (Docket No. 2003P–0300/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether diclofenac potassium 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Diclofenac potassium 25-mg tablet is the subject of NDA 20–142, approved in 1993 and held by Novartis Pharmaceuticals Corp. (Novartis). Diclofenac potassium is used for the treatment of osteoarthritis and rheumatoid arthritis. FDA has determined that shortly after the approval of NDA 20–142, Novartis made the decision not to market diclofenac potassium 25-mg tablet in the United States. It was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. FDA has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under § 314.161, has determined that diclofenac potassium 25-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list diclofenac potassium 25-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to diclofenac potassium 25-mg tablet may be approved by the agency.

Dated: November 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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